UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|---|-------------|----------------------|---------------------|-----------------|
| 10/535,039 | 05/03/2006 | Gyorgy Levay | 23299 | 2041 |
| 535 7590 12/13/2007 K.F. ROSS P.C. | | EXAMINER | | |
| 5683 RIVERDALE AVENUE | | | JAVANMARD, SAHAR | |
| SUITE 203 BOX 900 BRONX, NY 10471-0900 | | | ART UNIT | PAPER NUMBER |
| | | | 1617 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 12/13/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
|---|---|--------------|--|--|--|--|
| | 10/535,039 | LEVAY ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | SAHAR JAVANMARD | 1617 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>11 May 2005</u> . | | | | | | |
| | | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4) ☐ Claim(s) 1-31 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6) Claim(s) is/are rejected. | | | | | | |
| 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) 1-31 are subject to restriction and/or election requirement. | | | | | | |
| 8) Claim(s) 1-31 are subject to restriction and/or election requirements | | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| 11) I he oath or declaration is objected to by the Examiner. Note the attached office Action of Terms 10 10 10 | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | • | | | | | |
| | , | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4) Interview Summar Paper No(s)/Mail D | | | | | |
| Notice of Draftsperson's Patent Drawing Review (P10-946) Information Disclosure Statement(s) (PTO/SB/08) | 5) Notice of Informal | | | | | |
| Paper No(s)/Mail Date 6) Other: | | | | | | |

10/535,039 Art Unit: 1617

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Group I, claim(s) 1-29, are drawn to a method of preparation of pharmaceutical compositions suitable for the treatment and/or prophylaxis of malfunctions of memory and/or cognitive decline or prevention of decline of learning abilities using the compounds of formula I as shown in claim 1.
- II. Group II, claim(s) 1-29 and 31 are drawn to a method of treatment and/or prophylaxis of malfunctions of memory and/or cognitive decline or prevention of decline of learning abilities using the compounds of formula I as shown in claim
 1.
- III. Group III, claim(s) 30, is drawn to a pharmaceutical composition for the treatment or prophylaxis of malfunctions of memory and/or cognitive decline or prevention of decline of learning abilities which comprises compounds of formula I as shown in claim 1.

Application/Control Number:

10/535,039 Art Unit: 1617

The inventions listed as Groups I - III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

The alleged special technical feature is compounds of formula I. In this case, Blaschke (US Patent No. 5,034,391) discloses the use of pyridazinone derivatives for the treatment of cardiovascular diseases and hypertension (abstract).

As a result, no special technical features exist among the different groups because the inventions in Groups I-III fail to make a contribution over the prior art with respect to novelty and inventive step. In conclusion, there is a lack of unity of invention, and therefore restriction for examination purposes is proper.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

This application contains claims directed to more than one species of the generic invention. Therefore, in addition to the group election above, <u>Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of each genus</u> compound claimed for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. For example, applicant is required to define each of X, Y, R1, R2, R3, and R4, and any additional variables as required for the particular species of the compound of formula I in claim 1 and so on. Applicant is further required to elect a species as shown below:

Art Unit: 1617

1) a disease (i.e. Korsakoff syndrome, Alzheimer disease, etc...) such as from the list in claim 2.

Currently, claims 1 and 2 are generic.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

Application/Control Number:

10/535,039 Art Unit: 1617

are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

Application/Control Number:

10/535,039

Art Unit: 1617

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

10/535,039 Art Unit: 1617

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SJ

SREENI PADMANABHAN SUPERVISORY PATENT EXAMINER